SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
MAY 23, 2001

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, May 23, 2001 at 1:00 p.m. Mountain Daylight Time (MDT) as part of the Seventh NELAC Annual Meeting in Salt Lake City, UT. The meeting was led by its chair, Mr. William Ingersoll of the U.S. Navy, NAVSEA Programs. A list of action items is given in Attachment A. A list of participants is given in Attachment B. The committee's draft Appendix C, which was provided as a handout during the meeting, is given in Attachment C. *The purpose of the meeting was to address items of importance as identified in the committee's previously distributed meeting agenda.*

INTRODUCTION

The meeting began with a brief introduction and a review of the meeting's ground rules by the facilitator, Mr. Owen Crankshaw. Mr. Ingersoll then called the meeting to order and asked the members of the committee to introduce themselves. The committee then moved to the first order of business on their agenda.

PROPOSED CHANGES TO CHAPTER 3

Mr. Ingersoll stressed that the committee's discussion would focus on substantive changes. He requested that audience members submit any editorial comments pertaining to typographical errors to the committee in writing. Mr. Ingersoll then led a section-by-section review of the committee's proposed changes to Chapter 3. The following sections of Chapter 3 generated significant discussion:

3.2.1 Basic Qualifications

An attendee asked for clarification of the intent of the committee's proposed addition of 3.2.1 c to this section ("Completion of the applicable technical training requirements for at least one field of testing ..."). Specifically, the attendee asked for confirmation that there would be no cross-over between disciplines. In response, the committee expressed their belief that requiring assessors to be trained in all disciplines before they are allowed to assess any one discipline would be time-consuming and impractical. Consequently, the proposed language in 3.2.1 c requires that an assessor will have completed at least one technical training course in an appropriate discipline area prior to performing an on-site assessment. The committee noted that any assessor performing an assessment for a specific discipline in which he has not been trained may be accompanied by a technical specialist with expertise in that discipline.

There was moderate discussion of the committee's deletion of the requirement that assessors complete the NELAC Basic Assessor Training within two years of becoming an assessor. In response the committee noted that by policy the standard will not be implemented for two years and that the issue can be revisited in two years if appropriate training is not available at that time.

There was also moderate discussion of assessor expertise. In response to comments from the audience, the committee referenced Section 3.4.1.1 ("The accrediting authority determines the number and expertise of the assessment team and support personnel that are required to conduct the on-site assessment based on the type of assessment and the scope of accreditation of the accredited or applicant laboratory.")

3.2.3.1 Basic Training

There was little discussion of proposed changes to this section. Mr. Ingersoll pointed out that by deleting references to the day on which training in each of the subject areas will be held the committee has made the section less prescriptive.

3.2.3.2 Technical Training

An audience member noted that the word "macroinvertebrates" had been dropped from the third subgrouping in the biological technical discipline grouping. Noting that the word also did not appear in the 1999 or 2000 NELAC Standard, the committee agreed to add it so that the subgrouping reads "Freshwater/Marine/Estuarine Macroinvertebrates."

Further discussion of the technical disciplines focused on microbiology. An audience member asked whether there had been any committee discussion of subgroupings within the various microbiology groupings. The committee noted that the accrediting authority approves technical training courses and that there is flexibility within that approval. The only limitation is that each training course should be titled appropriately and deemed adequate by the accrediting authority for their assessors. The committee agreed to include this issue as a "parking lot" issue for future committee discussion to provide clarification so that the standard does not imply that the microbiology groupings are an "all or none" process.

One audience member suggested that the committee add wording to this section requiring that assessors pass a written examination. A second audience member disagreed. The committee deferred discussion of the issue for inclusion in discussion of their proposed Appendix B.

3.2.3.3 Refresher Training

Noting that there have been numerous discussions of an appeals process appropriate for situations in which there are differences in the interpretation of the NELAC Standard, audience members suggested that refresher training include a review of changes in interpretation of the NELAC Standard as well as changes to the standard, itself. After moderate discussion of the issue, the committee agreed to add a language bullet to the refresher training text box.

3.3.2 Follow-up On-site Assessments

An audience member requested clarification of the one change to this section, asking whether the follow-up assessment team must be made up of all the same individuals who performed the original

assessment. The committee explained that the section merely reflects a global editorial change to replace "assessor" with "assessment team" and that there had been no intent to require that the same assessors perform the follow-up assessment. After moderate discussion, the committee agreed to change the wording of the proposed change from "the assessment team" to "an assessment team" for clarification.

3.4 PRE-ASSESSMENT PROCEDURES

It was noted that the reference to Appendix C in the section heading was only intended as a placeholder. Nevertheless, the committee decided to delete the reference since Appendix C will not be presented to the Conference for vote at NELAC 7.

APPENDIX A

Following discussion of proposed changes to Chapter 3, Mr. Ingersoll turned the committee's attention to discussion of four appendices developed by the committee. He explained that the appendices were developed to promote the uniform and consistent assessment of laboratories. He further explained the committee's intention to recommend that Appendices A, B, and D be implemented immediately (accelerated implementation).

Ms. Marlene Moore led discussion of Appendix A, which constitutes a standard for NELAC basic assessor training. She stressed that the committee's interest in substantive changes that might prevent the appendix from being approved at NELAC 7 and urged audience members to submit editorial comments in writing. Ms. Moore explained that the appendix was based on International Laboratory Accreditation Cooperative (ILAC) document G4 and reworked to meet the needs of NELAC. It was developed as a standard for training rather than as a training course. Ms. Moore then led a section-by-section review of the document.

A.1 Introduction

There was moderate discussion of the introductory statements that the appendix "must be used by providers to design basic training courses" and "can also be used by accrediting authorities to evaluate the acceptability of existing basic training courses." Audience members were of the opinion that the use of the words "must" and "can" implied different standards for providers than for accrediting authorities. The committee agreed to strike the sentence, "It can also be used by accrediting authorities to evaluate...and by assessors to gain familiarity with the content of such courses."

A.2 Course Purpose

In subsequent discussion of the appendix it was suggested that assessors must be trained in how to evaluate the scope of accreditation in a generic form. Consequently the committee agreed that additional language be included in the first bullet of Section A..2 to read "and the competency of the laboratory to perform the test methods on the scope of accreditation."

A.3 Course Logistics

Audience members noted a disconnect between the flexibility suggested in the first sentence of A.3.1 (Duration) and the defacto duration of 36 hours provided in the last sentence of the same section. It was noted that the use of computer-based training is becoming more common and that this might greatly affect the duration of the basic assessor training course. The committee agreed to delete the last sentence of A.3.1 referencing 36 hours. At least one audience member suggested that the committee would still need to include some minimum duration. In subsequent discussion a member of the audience noted that video examples of expert assessors are excellent training tools and recommended that the committee consider the use of video examples in assessor training.

Members of the audience directed the committee's attention to the first sentence of the third paragraph of A.3.2 (Providers, Instructors, and Participants) which read, "Only accrediting authorities can approve training programs for their assessors." The issue of ensuring consistency between accrediting authorities was once again raised. In response the committee reminded the audience that there is no approval body in existence at this time. The committee also noted that training in and of itself will not ensure consistency. Many other elements exist in the NELAC structure to ensure consistency between accrediting authorities. These elements include reviews of accrediting authorities to ensure that they are providing adequate training for assessors, the sharing of information between accrediting authorities, and refresher training. At least one committee member suggested that consistency in the performance of the assessments is not necessary. The committee member suggested that consistency in the outcome of assessments is what is truly necessary. After moderate discussion the committee agreed to change the first sentence of the third paragraph of A.3.2 to read, "Accrediting authorities shall approve training for their assessors..." There was considerable discussion of the use of the word "approve." A representative of an accrediting authority noted that his state approves assessors as competent and accepts training course as adequate.

There was moderate discussion of the 70% passing score required in A.3.4 (Final Examination). Audience members inquired about the impact of the required passing score on individuals who have already completed assessor training. The committee noted that the requirement is not retroactive.

A few members of the audience questioned the value of the "Certificate of Attendance" mentioned in A.3.5 (Attendance or Completion Certificate). In response the committee explained that they anticipate that attendance at the courses will extend beyond the assessor community to include interested parties such as laboratory personnel.

A.4 Course Contents

Audience members recommended adding "Scope of Accreditation" to the list of NELAC items constituting A.4.3 (Fundamentals of NELAC and and National Environmental Laboratory Accreditation Program [NELAP]). The committee readily agreed to this addition.

Audience members also noted that the appendix did not address the topic of Technical Directors (qualifications, grandfathering, exempting, etc.). After moderate discussion the committee agreed to

add "Personnel Qualifications" to the list of items constituting A.4.5 (Accreditation of Laboratories). Citing redundancy with the mention of "accreditation process" in the first sentence of A.4.5, the committee also agreed to strike item 2 ("Accreditation Process") and to move the remaining items up so that they were equally weighted.

As the time allotted for discussion of Appendix A was ending, a member of the audience suggested revisions to A4.11.2.3 (On-site Assessment Proper). The committee readily agreed to the addition of a sixth item ("Records Retention and Reporting") to the section and deleted "uncertainty of measurements" as a sub-item under item 4.. They deferred as a "parking lot" issue for future committee discussion a recommendation that they consider more complete information under item 5 (Data and Document Review).

The final change to Appendix A made by the committee was the deletion of A.5 (Performance Based Measurement System (PBMS)) pending revisions to Chapter 5. In conclusion Ms. Moore urged attendees to provide additional comments on Appendix A as they use the appendix.

APPENDIX B

Mr. Jack Hall led discussion of Appendix B. He explained that Appendix B provides guidance for anyone preparing a technical training course for assessors or modifying an existing technical training course. An audience member expressed the opinion that NELAC has neither the size nor the capacity to develop technical training courses. He suggested that there are technical courses already in existence, but that existing courses may require the development of a second course on how to take technical training and convert it into how to perform an on-site assessment. In discussion of the issue the committee noted that the purpose of technical training courses for assessors is not training in the technology itself. The purpose of technical training is training in how to adequately assess the pertinent technology. Substantial discussion of technology ensued.

Audience members questioned the requirement that assessors complete the NELAC Basic Assessor Training prior to taking technical training courses. The committee readily agreed to strike the requirement.

In subsequent discussion of the proposed accelerated implementation of Appendix B, Ms. Jeanne Hankins, NELAP Director, reminded the committee that the policy on accelerated implementation of the NELAC Standard is that the NELAP accrediting authorities must be able to accomplish what is outlined in the standard. She noted that the accrediting authorities cannot meet the technical training requirements outlined in Appendix B because the courses are not available at this time. Explaining that the inability to meet the requirements of the standard would delay approval of accrediting authorities, Ms. Hankins suggested that the appendix require a two-year delay in implementation. There was substantial discussion of proposing accelerated implementation of only Appendix A. The committee explained that their rationale for accelerated implementation is to provide a standard against which technical courses should be developed. The committee also referenced Chapter 3, Section 3.2.1 and suggested that the training clock does not start until training courses are developed.

An audience member noted that the impact of differences in technical experience on the training process is not addressed in Appendix B. In response the committee pointed out that it is the responsibility of the accrediting authorities to judge the qualifications of their assessors. The committee suggested that the standard should not attempt to be prescriptive in regard to experience requirements. A member of the audience asked if it is possible to test out of a technical training course if the assessor has the appropriate experience. The committee noted that even individuals with extensive technical experience have usually not been trained in what must be examined to determine if an individual is doing something wrong. Another member of the audience suggested that a separate course on inappropriate practices, apart from technology, is needed.

Noting that Performance Based Measurement System (PBMS) terminology will change pending approval of revisions to the NELAC Standard, audience members recommended striking all references to PBMS. The committee agreed to this change.

As the time allotted for discussion of Appendix B drew to a close, members of the audience reminded the committee that it will be difficult to assess B.3 (Course Objectives) until assessors have actual courses developed against this standard. The committee agreed.

APPENDIX C

Appendix C was not provided in meeting packets, but was provided as a handout for the committee meeting. Mr. Ingersoll informed attendees that the draft version of Appendix C, which constitutes minimum elements for accrediting authority standard operating procedures (SOPs) for on-site assessments, will not be presented to the Conference for a vote at NELAC 7. He noted that the committee anticipates presenting the appendix for a vote at the Eighth NELAC Annual Meeting (NELAC 8) and is greatly interested in input from NELAC stakeholders. Ms. Mimi Uhlfelder led a section-by-section review of Appendix C. The following sections generated significant discussion:

Pre-Assessment, 2. Assessment Team

There was considerable discussion of the detection of improper or potentially illegal activities and of whether the decision to terminate the assessment should be communicated to the laboratory. A representative of one of the eleven currently approved NELAP accrediting authorities noted that procedures related to the detection of improper or potentially illegal activities are internal accrediting authority procedures and are not applicable to the laboratory. In the interest of clarification the committee agreed to split the pertinent sentence into two sentences. The two sentences will now read as follows: "The SOP shall also include assessment team procedures followed if improper or potentially illegal activities are encountered. The SOP shall detail the circumstances under which the assessment team communicates this to the accrediting authority."

Pre-Assessment, 3. Document Review

There was considerable discussion of preliminary document review. It was noted that the number and volume of documents required for submission to the accrediting authority prior to the on-site assessment is quite large. It was also noted that the language of the Pre-Assessment Document Review section should be clarified to distinguish between preliminary document review and on-site document review. In response to these concerns, the committee agreed to move the fourth sentence of the section ("The SOP shall describe how the assessment team will identify and select specific documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.12.") to the beginning of the section. A representative from an accrediting authority asked whether an accrediting authority is within its authority to require a laboratory to submit all documents for review prior to the assessment. In subsequent discussion the committee noted that the standard is not specific in regard to this issue. The committee referred the commenter to Chapter 3, Section 3.4.3, which reads, "Prior to initiating an on-site assessment, the assessment team shall make determinations as to which laboratory records they wish to review prior to the actual visit." It was noted that this section would benefit from wordsmithing to distinguish the requirements for a follow-up assessment from the original assessment. There was also considerable discussion of whether the accrediting authority should present preliminary findings to the laboratory if the accrediting authority determines that the laboratory is not ready for an on-site assessment. The committee agreed to add "will be used" to the pertinent sentence such that it will now read, "Findings or observations made during this preliminary review will be used to determine if the laboratory is ready for an on-site assessment." The committee also agreed that the laboratory should be contacted, at a minimum, if the assessment team must cancel an on-site assessment that has already been scheduled. They did not reach consensus on whether the accrediting authority must present preliminary findings to the laboratory. Consequently, they deferred discussion of this issue for a future committee meeting.

A representative from an accrediting authority asked whether it is the committee's intent that every state must take Appendix C and prepare one identical SOP. He noted that the Accrediting Authority Workgroup has agreed to establish a subcommittee to prepare a baseline or generic SOP for on-site assessments. The subcommittee recognizes that there may be specific state statutes that preclude the adoption of the generic SOP by all accrediting authorities. In response the committee pointed out that Appendix C is not an SOP. It is the standard for developing an SOP. The committee noted that they had tried to be sensitive to the needs of the accrediting authorities in including only the requirements of the NELAC Standard rather than interpretations of the standard. The committee only provided examples for the purposes of clarification. The committee also noted that Appendix C can be used by the group reviewing an accrediting authority's SOP for on-site assessments.

Pre-Assessment, 5. Confidential Business Information (CBI)

Noting that states may be bound by state regulations rather than federal regulations, the committee agreed to add language to the this section such that it now reads, "...in compliance with federal and/or state regulations...." A commenter recommended that the committee also review Section 3.4.5 of Chapter 3 (CBI Considerations) to ensure consistency between the chapter and Appendix C. The committee deferred the issue for future action.

Assessment, 3. Assessment Areas

It was noted that there is no reference to waste management as an area to be examined during the on-site assessment. In response the committee noted that although Chapter 5 requires that the laboratory's SOP include a section addressing waste management, the NELAC assessment process does not require determining whether the laboratory is meeting the requirements of applicable regulations for waste management.

Assessment Reporting, 1. Assessment Report

In response to audience comments the committee confirmed that there is no specification in Appendix C for the format of the assessment report. A member of the audience pointed out a minor typographical error in the second sentence of this section. "...Identification if participants..." should be changed to "...identification of participants...."

Assessment Reporting, 3. Report Release

Ms. Hankins pointed out that assessment reports will not be included in the national database and suggested the committee review Section 3.7.4 of Chapter 3 (Release of On-site Assessment Report). The committee deferred this issue for future action.

Assessment Closure, 2. Roles and Responsibilities

It was suggested that the committee clarify the wording of this section to address how the assessment results feed into the accreditation process.

Assessment Closure, 3. Follow-up Assessments

A member of the audience suggested that the committee give some attention to the minimum documentation required for a follow-up assessment. It was also noted that this issue links to the Pre-Assessment Document Review section discussed earlier.

APPENDIX D

Mr. Alfredo Sotomayor led discussion of Appendix D, which constitutes critical performance elements of test methods and assessment procedures. Mr. Sotomayor explained that Appendix D was originally developed as Appendix B-2. After recognizing that Appendix B-2 was not well-matched with technical training, the committee decided to pull information related to methods evaluation into its own appendix. Members of the audience asked why the committee considered Appendix D necessary. Mr. Sotomayor explained that the committee had received comments from audience members at the last two NELAC meetings indicating that the NELAC Standard should contain some guidance for assessors on how to actually perform an assessment. Appendix D is the committee's attempt to provide such guidance by describing the critical performance elements that the assessor must review to evaluate methods and/or SOPs. One issue of debate is whether the assessor will evaluate methods or

SOPs. In subsequent discussion of the issue, members of the committee pointed out that the NELAC glossary definition of test method is not the mandated method. A member of the audience also pointed out that the international definition of "accreditation" is the determination that an entity is competent to perform specific tests or types of tests. The committee noted that the NELAC Standard as written requires assessors to evaluate test methods and SOPs (reference Section 3.6.1 g of Chapter 3). Whether the standard requires assessors to evaluate every test method or a representative sampling of test methods is open to debate. There was moderate discussion of guidance on how to sample the scope of accreditation and the level of evaluation each test method will get.

Several members of the audience expressed the opinion that much of the information in Appendix D is already in Chapter 5 of the NELAC Standard. It was also suggested that the information in Appendix D is confusing, making the appendix impractical for use. Some attendees expressed the opinion that there is no need for Appendix D. After considerable discussion, it was suggested that the appendix is not yet ready for presentation to NELAC for a vote. It was also suggested that the generic SOP to be prepared by the Accrediting Authority Workgroup would include at least some of the information in the committee's proposed Appendices C and D. Perhaps the two could be integrated with the Accrediting Authority Workgroup's product into one minimal requirements document. In response the committee pointed out that the generic SOP prepared by the Accrediting Authority Workgroup may meet the needs of the first eleven approved accrediting authorities, but may not meet the needs of new accrediting authorities.

There was considerable discussion of the use of the words "acceptable and appropriate for the intended purpose" in D3 (Critical Performance Elements). Suggesting that this language is highly subjective, members of the audience asked how one can assess "acceptable and appropriate." It was recommended that the language be changed to ensure that in all cases assessors must confirm that the critical performance elements areas are in compliance with the NELAC Standard. Although some audience members suggested that it is the responsibility of the data consumer to determine that the method is appropriate for the intended purpose, other audience members noted that many data consumers are counting on the laboratory to do what is appropriate and acceptable. Members of the committee also noted that the laboratory is often not informed of the intended purpose of the analysis.

In further discussion a member of the audience recommended that the committee review ISO Guide 2 regarding the use of "compliance" versus "conformance." Another member of the audience noted that PT samples are not discussed, to which the committee responded that PT samples are not part of the on-site assessment.

In conclusion the committee announced that Appendix D would not be submitted for vote at NELAC 7. The committee will continue to develop the appendix to be submitted for vote at NELAC 8.

ADDITIONAL COMMENTS

With little time remaining in the committee's allotted meeting time, Mr. Ingersoll called upon Mr. David Friedman to present the results of a PBMS on-site assessment experiment. Mr. Friedman explained that he has often held the position that it is not critical to use the NELAC approach to on-site assessments in order to arrive at an acceptable conclusion. He explained that his PBMS approach is based on the following four questions:

- Does the laboratory have in place a quality system that will ensure that the laboratory generates and reports data of known and documented quality?
- Is the laboratory actually following its quality system?
- Do the laboratory staff demonstrate competence to do their work?
- Are the laboratory's facilities and equipment adequate to do the work?

Mr. Friedman explained that his thesis is that a "yes" answer to the four questions serves the function of determining that a laboratory is qualified to generate data of known and documented quality but does not identify all NELAC deficiencies. His approach focuses on quality of data rather than on things he considers management prerogative as to how laboratory performs its work. Mr. Friedman noted that his approach will determine if there are significant problems in the laboratory that need correction, but will not examine every item identified in Chapter 5 of the NELAC Standard.

Mr. Friedman further explained that his procedure focused on the big picture with spot-checks to identify where failures may occur in major systems. The process began with an examination of quality system documentation, training documentation, etc., and then moved to a review of data packages to determine if there was evidence that the laboratory was actually following its quality system. He noted that the PBMS approach is more focused on client needs to ensure that the data reported to the client meets its intended purpose and that the laboratory can demonstrate that they know their data is valid.

Ms. Moore followed the NELAC approach to the on-site assessment. Although the two procedures were radically different, they yielded comparable evaluations of the laboratory. The committee learned several lessons from the experiment. There are a number of approaches that will allow an assessor to reach the same common conclusion. The PBMS approach is a valid approach. Assessor competency in the specific technology being evaluated is not necessary for an effective assessment. Training will be needed to teach assessors a new paradigm so that they don't just check boxes on a checklist, but understand the importance of what they are checking. Assessors must be trained in the process of sorting out whether a deficiency indicates a system failure or a random human error. Subsequent discussion from the floor on the committee's on-site assessment experiment suggested that a combined approach (PBMS and NELAC-specific) might be useful.

There was moderate discussion from the floor concerning the need for and value of an assessment checklist. Ms. Moore noted that although she tends not to be a checklist assessor, she still carries a checklist. She noted that most assessors need a checklist to be used as a tool to make sure that they

cover all the elements of the standard. The checklist also becomes documentation of what the assessor has covered. It was noted that there are sixteen elements in Chapter 5 of the NELAC Standards. A member of the audience asked why it is necessary to cover all sixteen elements if the assessor identifies a major deficiency early in the assessment. In response a representative of an accrediting authority explained that in assessing a laboratory his assessors are notifying the laboratory of the areas in which they need to improve. He suggested that the NELAC process is still in the mode of bringing laboratories up to speed and that assessors cannot help laboratories with things that they have not examined. A representative of another accrediting authority mentioned the issue of time and resources. He noted that the accrediting authority must eventually ask, "Must I send out a team for a follow-up assessment or can I accept a corrective action report?" The assessment checklist is often used as documentation in answering this question.

CONCLUSION

The committee's allotted meeting time having expired, Mr. Ingersoll thanked everyone in attendance for their input. The meeting was adjourned shortly after 5:00 p.m. MDT.

Attachment A

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
MAY 23, 2001

Item No.	Action	Date to be Completed
1.	Committee will present Chapter 3, Appendix A (accelerated implementation), and Appendix B (accelerated implementation), as modified in this meeting, for approval at NELAC 7 voting session.	NELAC 7
2.	Committee will consider clarification of language in 3.2.3.2 pertaining to technical training course groupings (specifically microbiology) for flexibility.	NELAC 7i
3.	Committee will consider expanded language on Data and Document Review in Appendix A Section A.4.5.	NELAC 7i
4.	Committee will consider expanded language on Document Review in Appendix C, Pre-assessment Section 3 (specifically issue of whether accrediting authority must preliminary findings to laboratory).	NELAC 7i
5.	Committee will review CBI language in Chapter 3 Section 3.4.5 to ensure consistency with Appendix C.	NELAC 7i
6.	Committee will review Chapter 3 Section 3.7.4 to parallel the Appendix C section on Assessment Reporting (release to national database).	NELAC 7i
7.	Committee will continue development of Appendix C in response to comments received at NELAC 7.	NELAC 8
8.	Committee will continue development of Appendix D in response to comments received at NELAC 7.	NELAC 8

Attachment B

PARTICIPANTS
ON-SITE ASSESSMENT COMMITTEE MEETING
MAY 23, 2001

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APPENDIX C - Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.

Introduction

Chapter 6 of the NELAC standards defines the process and criteria used by NELAP to determine whether an accrediting authority meets the standards required for recognition. Under this standard (Section 6.2.3.a.1), accrediting authorities are required to maintain documentation about the laboratory accreditation process. Section 6.3.3.1.3.b.8 also states that the accrediting authority's Quality Manual shall include the policies and procedures to implement the accreditation process.

This appendix summarizes the elements to be included by accrediting authorities in SOPs describing on-site assessments of laboratories seeking accreditation under the NELAC standards. At a minimum, the following elements shall be included in the SOPs to ensure consistency of laboratory assessments performed by accrediting authorities.

Pre-Assessment

1. Assessment Planning: The SOP describes how the type of assessment is determined, e.g., initial, renewal, follow-up, etc. Also includes procedures for determining whether the assessment is announced or unannounced, the scope of accreditation (technology, matrix, method, analyte or analyte groups), the estimated time spent on-site, and the assessment team resources needed. The SOP will also address preparation of the on-site assessment agenda.

2. Assessment Team: The SOP describes the qualifications, roles, and responsibilities of the assessment team members, e.g., lead assessor, assessors, and technical support personnel. The SOP shall also include assessment team procedures followed if improper or potentially illegal activities are encountered and details the circumstances under which the assessment may be terminated including how the assessment team communicates this to the accrediting authority.

3. Document Review: A preliminary document review is performed prior to the on-site assessment. Findings or observations made during this preliminary review determine if the laboratory is ready for an on-site assessment. The accrediting authority may present preliminary findings before the on-site assessment so the laboratory has time to correct before the assessment team arrival. The SOP shall describe how the assessment team will identify and select specific documents and records for review before and during an on-site assessment as required in NELAC Sections 3.4.3, 3.5.3, and 5.12. Those records shall include the laboratory's accreditation application, previous assessment and PT reports, laboratory organization charts, qualifications statements for all staff involved in the analysis or reporting of results, the laboratory QA manual, SOPs for the fields of testing for which accreditation is sought, laboratory instrumentation and equipment records, standard and reagent preparation documentation, initial method validation studies, Demonstration of Capability test method precision and accuracy records, sample receipt and handling, internal audit records, and the laboratory's annual management review. Other documents required for review should be described in the SOP: Document control records, corrective action records, complaints records, subcontracting registry, uncertainty calculations (currently needed for WET and Radiochemistry), and an example client report.

4. Accrediting Authority Standardized Assessment Documents and Forms: The SOP describes the documents required for the assessment, and which should be assembled prior to the assessment, e.g., Confidentiality Notice, Conflict of Interest Form, Assessor Credentials, Assessment Notification Letter, Attendance Sheets for opening and closing conferences, standardized NELAC checklists, and Assessment Appraisal Forms.

APPENDIX C - Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.

5. Confidential Business Information: Explains the procedures for handling confidential business information in compliance with federal regulations (40 CFR Part 2).
6. National Security Considerations: The SOP describes procedures for handling security requirements at Federally owned or operated facilities.

Assessment

1. Opening Conference: The SOP describes procedures for the opening conference and details the topics to be covered, including the scope of the assessment, the schedule with a tentative time for the exit conference, the NELAC standards used for the assessment, identification of the assessment team, test methods to be examined, records and SOPs required, Confidential Business Information, roles and responsibilities of the laboratory staff, the Assessment Appraisal Form, laboratory questions about the assessment process, and laboratory safety procedures to be followed by the assessment team (lab coats, safety glasses, etc.).
2. Records Review and Collection: In general the assessment team must determine the extent of traceability of standards, personnel training, documents, samples, data, records and problems/resolution (corrective action/follow-up). The SOP describes the procedures to be followed for records review by the assessment team during the on-site visit and the criteria the assessment team will use to determine the accuracy and completeness of the records reviewed or collected during the assessment, e.g., data review includes tracing samples from receipt to verification of final results, training records review includes a representative sampling from all operational and support areas, etc.
3. Assessment Areas: The SOP describes the areas to be evaluated against NELAC Chapter 5 standards during the assessment, e.g., the laboratory facility, laboratory organization and management, qualifications of laboratory staff, sample handling including receipt and tracking, instrumentation, standards traceability, test methods, data reduction and reporting procedures, and quality control procedures. Additionally, the SOP defines what is objective evidence of conformance to the standard, e.g., records or words or just assessor observation. The SOP also describes the procedures to determine the compliance tools to be used in evaluation of these areas
4. Staff Interviews: The SOP describes the procedures for conducting staff interviews.
5. Closing Conference: The SOP details the procedures to be followed for the closing conference, including the presentation process of deficiencies at the closing conference (written, checklist, verbal), discussion of deficiencies, notification that the assessment team may identify additional deficiencies in the final report, handling disputed findings, when to expect the assessment report, and schedule for renewal and reassessment.

Assessment Reporting

1. Assessment Report: The SOP describes the requirements for the final site report, including the format. The assessment report shall contain the name and address of the audited organization, the date of the assessment, identification and affiliation of the each assessment team member, identification if participants in the assessment, a statement of the objective of the assessment, summary, identification of deficiencies with reference to the specific NELAC standard(s), and comments and recommendations.
2. Roles and Responsibilities: The SOP addresses the roles and responsibilities of the accrediting authority and the assessment team in the report generations, distribution, and release procedures.

APPENDIX C - Minimum Elements for Accrediting Authority Standard Operating Procedures For On-Site Assessments.

3. Report Release: The SOP describes the requirements for release of the assessment report to the laboratory, to the National Accreditation Database and to the public. The SOP shall address exemptions to the release of proprietary information.

Assessment Closure

1. Evaluation of the Laboratory's Corrective Action Plan: The SOP describes the accrediting authority's procedures for evaluating the laboratory's corrective action plan.
2. Roles and Responsibilities: The SOP details the roles and responsibilities of the assessment team and the accrediting authority in the evaluation of the laboratory's response and the determination of accreditation status.
3. Follow-up Assessments: The SOP describes the circumstances under which a follow-up assessment would be necessary.
4. Record Retention: The SOP defines the record retention policy for documentation used in or obtained during an assessment, including assessment reports, checklists, and laboratory responses.